

underload in the amount of pressure placed on a leg.

(b) *Classification.* Class II (performance standards).

§ 890.5650 Powered inflatable tube massager.

(a) *Identification.* A powered inflatable tube massager is a powered device intended for medical purposes, such as to relieve minor muscle aches and pains and to increase circulation. It simulates kneading and stroking of tissues with the hands by use of an inflatable pressure cuff.

(b) *Classification.* Class II (performance standards).

§ 890.5660 Therapeutic massager.

(a) *Identification.* A therapeutic massager is an electrically powered device intended for medical purposes, such as to relieve minor muscle aches and pains.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996]

§ 890.5700 Cold pack.

(a) *Identification.* A cold pack is a device intended for medical purposes that consists of a compact fabric envelope containing a specially hydrated pliable silicate gel capable of forming to the contour of the body and that provides cold therapy for body surfaces.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.5710 Hot or cold disposable pack.

(a) *Identification.* A hot or cold disposable pack is a device intended for medical purposes that consists of a sealed plastic bag incorporating chemicals that, upon activation, provides hot or cold therapy for body surfaces.

(b) *Classification.* Class I (general controls).

§ 890.5720 Water circulating hot or cold pack.

(a) *Identification.* A water circulating hot or cold pack is a device intended for medical purposes that operates by pumping heated or chilled water through a plastic bag and that provides hot or cold therapy for body surfaces.

(b) *Classification.* Class II (performance standards).

§ 890.5730 Moist heat pack.

(a) *Identification.* A moist heat pack is a device intended for medical purposes that consists of silica gel in a fabric container used to retain an elevated temperature and that provides moist heat therapy for body surfaces.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.5740 Powered heating pad.

(a) *Identification.* A powered heating pad is an electrical device intended for medical purposes that provides dry heat therapy for body surfaces. It is capable of maintaining an elevated temperature during use.

(b) *Classification.* Class II (performance standards).

§ 890.5765 Presssure-applying device.

(a) *Identification.* A presssure-applying device is a device intended for medical purposes to apply continuous pressure to the paravertebral tissues for muscular relaxation and neuro-inhibition. It consists of a table with an adjustable overhead weight that, in place of the therapist's hands, presses on the back of a prone patient.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63015, Dec. 7, 1994]